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TITLE:	<b>INTESTINAL BYPASS DEVICE TO TREAT OBESITY</b>

This application claims priority to U.S. Provisional Application No. 60/424,248 filed 11/06/2002.

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## BACKGROUND OF THE INVENTION

[0001] The present invention relates to surgical devices to treat obesity. More particularly, the present invention relates to surgical implants for causing weight loss.

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[0002] Obesity is a serious health problem especially in developed countries. Approximately 60 million adults in the U.S. are obese. Obesity leads to several health problems such as increase of risk of illness and death due to coronary artery disease, diabetes, stroke, hypertension, and kidney and gallbladder disorders and some types of cancer. It also increases the risk of developing osteoarthritis and a condition called sleep apnea defined as periodic cessation of breathing during sleep (Source: Medline). Obesity also causes several psychosocial problems like depression and loss of self-esteem.

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[0003] Obesity has high medical costs due to the high prevalence of obesity and the various health problems associated with it. In a study conducted in 1998, the direct medical costs due to obesity were estimated to be \$51.64 billion in the US (Source: Website of the American Obesity Association). These costs could increase in the future as the prevalence of obesity is steadily increasing. In the United States, the percentage of children and adolescents who are obese

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has doubled in the last 20 years. Thus, there is an urgent need to treat this serious health problem.

[0004] Obesity is treated by reducing the patient's weight. Although several methods are available to achieve weight loss, none of them have been entirely successful in causing the desired weight loss. Weight loss methods can be broadly divided into diet modification, exercise therapy, pharmacological therapy and surgical procedures. The most common method of weight loss is diet modification. The aim of diet modification techniques is to reduce the number of calories that are consumed by the patient. However, the success of a weight loss program based on diet modification critically depends upon the patient strictly following the prescribed diet.

[0005] Exercise therapy causes weight loss through aerobic exercises. Like diet modification methods, the success of a weight loss program based on exercise therapy critically depends upon the patient regularly performing the prescribed exercises.

[0006] Pharmacological therapy uses specific medications that cause weight loss. However, the use of weight loss medications causes side effects. Further, when the weight loss medications are discontinued, the lost weight is regained.

[0007] Surgical procedures are used for weight loss when diet modification, exercise therapy and pharmacological therapy fail to cause required weight loss. The most commonly used surgical procedures for weight loss are Roux-en-Y gastric bypass procedure, restrictive gastric operations, malabsorptive operations such as biliopancreatic diversion and intestinal bypass procedure. The Roux-en-Y gastric bypass procedure involves creating a stomach pouch out of a small portion of the stomach and attaching it directly to the small intestine, bypassing a large part of the stomach and duodenum. The small stomach pouch holds much smaller amounts of food at a time, and hence the patient experiences a feeling of satiety even after eating a small quantity of food. Also, fat absorption from food is substantially reduced as the food bypasses a large portion of the duodenum.

[0008] Restrictive gastric operations cause weight loss by restricting the food intake by the patient. A portion of the stomach is surgically modified to form a small pouch. The food enters the pouch from the esophagus. The outlet from the pouch to the rest of the stomach is restricted. This restriction delays the emptying of food from the pouch, causing a feeling of fullness even after consuming small amounts of food.

[0009] Malabsorptive operations such as biliopancreatic diversion cause weight loss by restricting the food intake and also by reducing the fraction of calories absorbed by the body from the digested food. In a biliopancreatic diversion, portions of the stomach are removed along with the duodenum and the jejunum. This reduces the fraction of calories absorbed from the digested food, thereby causing weight loss.

[0010] Conventional intestinal bypass procedures cause weight loss by removing a portion of the small intestine and reconnecting the remaining portion of the small intestine. Removal of a portion of the small intestine reduces the effective length of the small intestine. This reduces the amount of nutrients that are absorbed by the body from the food and causes weight loss. It is also associated with severe side effects.

[0011] The abovementioned surgical procedures are highly invasive and require major modifications to the patient's anatomy. Further, the anatomical modifications due to these procedures cannot be frequently adjusted to adjust the rate of weight loss. Also, if these surgical procedures cause severe side effects to the patient, the anatomical modifications cannot be reversed easily.

[0012] There are several surgical procedures for causing weight loss that use implants like intragastric balloons and vagus nerve stimulation devices. Intragastric balloons cause weight loss by occupying a significant portion of the stomach lumen and inducing a feeling of satiety in the patient. However, the intragastric balloons cannot be easily adjusted on a regular basis to adjust the rate of weight loss. Vagus nerve stimulation devices stimulate the vagus nerve of a patient by electrical currents to produce a sensation of satiety. Vagus nerve stimulation devices face the problems of accidental stimulation and potential of harm to the patient in the presence of strong electromagnetic fields. Also they have been associated with unpleasant side effects.

[0013] Thus, there is a need for an obesity treatment that does not need significant modifications to the patient's anatomy. Further, there is a need for an obesity treatment whose parameters can be adjusted frequently to adjust the rate of weight loss. Further, there is a need for an obesity treatment whose parameters can be adjusted with minimal discomfort to the patient. Further, there is a need for an obesity treatment that can be easily reversed if the patient experiences significant side effects.